IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

IN RE: TESTOSTERONE REPLACEMENT THERAPY PRODUCTS LIABILITY LITIGATION	MDL No. 2545 Master Docket Case No. 1:14-cv-01748 Honorable Matthew F. Kennelly
This document applies to: MDL NO. 2545 Master Docket Case No. 1:14-cv-01748	

PLAINTIFFS' STEERING COMMITTEE'S OMNIBUS RESPONSE IN OPPOSITION TO ABBVIE'S "REQUESTS TO ADOPT PRIOR MOTION *IN LIMINE* RULINGS"

August 29, 2018

Introduction

Plaintiffs respectfully submit this omnibus response in Opposition to AbbVie's "Requests to Adopt Prior Motion *In Limine* Rulings," which is included in each of its case-specific Wave 1 omnibus MIL briefs. The parties have come to resolution on five of AbbVie's requests (a, e, g, k,[1] and l[2]). Plaintiffs continue to object to, or otherwise dispute the language/framing of, seven of AbbVie's requests (b, c, d, f, h, i, and j), which Plaintiffs address, *infra.* This omnibus brief is being filed on the master docket and the following individual dockets: Cecile Frost v. AbbVie Inc., *et al*., Case No. 1:15-cv-01484; Gordon Abraham, *et al*., v. AbbVie Inc., *et al*., Case No. 1:15-cv-05009; Dick Bechtholdt v. AbbVie Inc., *et al*., Case No. 1:15-cv-09652; Edwin Clay Harris v. AbbVie Inc., *et al*., Case No. 1:14-cv-07963; George Kibat v. AbbVie Inc., *et al*., Case No. 1:15-cv-08820; Edward Natale, Jr. and Barbara-Anne Natale v. AbbVie Inc., *et al*., Case No. 1:16-cv-05706; and Dominick Papandrea *et al*., v. AbbVie Inc., *et al*., Case No. 1:14-cv-08948. The Court granted Plaintiffs' request to file the instant twelve-page omnibus brief (Dkt. 2851) on August 27, 2018 (Dkt. 2856).

Plaintiffs' Opposition to AbbVie's Request (b)

"Plaintiff will not assert a claim that AbbVie defrauded the FDA or that the FDA would have acted differently on the basis of other information. Plaintiff may present evidence of what information AbbVie provided to, or withheld from, the FDA and the FDA's response or non-response to such information. (*In Re Testosterone Replacement Therapy Prod. Liabl. Litig. Coordinated Pretrial Proceedings*, No. 14 C. 1748, 2017 WL 1836443, at *20 (N.D. Ill. May 8, 2017; CMO 59, p. 2)."

[1] The parties have agreed to the following modification to AbbVie's request (k): "Plaintiff will not introduce Exhibits 145 (emails and consultant notes from mock advisory committee) and 905 (August 7, 2014 email regarding advisory committee briefing document), which are comments made by third parties. (Konrad II Tr. p. 2075)."

[2] The parties have agreed to the following modification to AbbVie's request (l): "If introduced, Plaintiff will redact the third sentence of Exhibit 608, stating "I am not changing my practice, but I had a doctor say to me today 'testosterone kills." (Konrad II transcript, p. 2073)

Response:

AbbVie's recitation of the Court's ruling here continues to be unfairly lopsided in its favor and, at bottom, simply an incomplete statement of how the Court how has addressed it.

Although the issue has come up on several occasions during the first bellwether trials, the two seminal rulings on it were the Court's order denying summary judgment on "off-label" claims and its *in limine* order before the first *Mitchell* and *Konrad* trials. *See* CMO No. 48, Doc. No. 1897, at *43; and CMO No. 59, Doc. No. 1966, at *1-2. To re-orient the Court, at summary judgment AbbVie made a variety of arguments attempting to cast certain of Plaintiff's claims as "fraud-on-the-FDA"-based, repeatedly conflating Plaintiff's *evidence* with their actual *claims*. Rejecting AbbVie's characterizations, the Court correctly observed, *inter alia*:

> Plaintiffs say they are not challenging the FDA's approvals [] to support a claim of fraud on the FDA, and the Court agrees that plaintiffs cannot advance claims along these lines. But the testimony is properly admissible, in the Court's view, to attempt to show that AbbVie and its predecessors conveyed misleading information to physicians and patients concerning the safety and efficacy of the product.

CMO No. 48, Doc. No. 1897, at *43; *see also id.* at *13-16 (rejecting preemption arguments). When AbbVie again raised this issue *in limine* before *Mitchell* and *Konrad*, the Court again clarified:

> On this issue, the Court has already ruled that plaintiffs may not assert a claim that AbbVie defrauded the FDA or that the FDA would have acted differently on the basis of other information. The Court has also ruled, however, that evidence of what information AbbVie provided to, and withheld from, the FDA is relevant to plaintiffs' claims that AbbVie misled the public, including plaintiffs and their prescribing physicians. AbbVie argues that any information it withheld from the FDA is information it was not required to submit, and thus withholding that information was not misleading. AbbVie will be free to press this point on cross-examination. Plaintiffs may introduce evidence that AbbVie's submissions to the FDA misled the public; AbbVie's arguments to the contrary go to the weight, rather than the admissibility, of that evidence. AbbVie's motion to exclude evidence of information it submitted to the FDA is denied.

CMO No. 59, Doc. No. 1966, at *2 (internal citations omitted).

Underscoring the need for clarity on this issue, AbbVie has repeatedly tried to use the Court's ruling protecting it from a "fraud-on-the-FDA" claim as a sword to improperly attack Plaintiff's evidence at trial. For instance, as the Court might recall, in *Mitchell II*, AbbVie counsel attempted to suggest that the absence of such a "claim" essentially meant that Plaintiff was not really charging AbbVie with any misconduct, *see*, *e.g.*, Mitchell II Tr.[3], at 823:19—825:18, and then tried to drive that misrepresentation home to the jury in his closing slides. *Id.* at 2797:25—2802:9.

This gamesmanship should not be permitted going forward. Unfortunately, AbbVie's current proposal would not curtail, but only invite, more of the same, and so AbbVie's language misses the mark. Instead, Plaintiffs propose the following language for a global order on this issue:

> Plaintiffs have not pleaded legal "claims" for fraud on the FDA. Instead, Plaintiffs have "evidence" showing what information and materials AbbVie provided or did not provide to FDA. Plaintiffs are free to offer that evidence in support of their arguments that AbbVie misled the FDA, and by extension misled the public, the medical community, and consumers, as to the safety and efficacy of AndroGel. That evidence and those arguments, if presented and if made, are relevant to Plaintiffs' state-law-based common law claims for relief, including negligence, negligent misrepresentation, fraud, and punitive damages.

Plaintiffs' Opposition to AbbVie's Request (c)

"Plaintiff will not introduce evidence of alleged misconduct by other TRT manufacturers, except that plaintiff is allowed to introduce evidence of communications from the FDA to other TRT manufacturers that AbbVie received and put AbbVie on notice, including the FDA's 2010 letter to Slate Pharmaceuticals regarding Testopel. (CMO 59, pp. 6-7)."

Response:

The Court has not foreclosed the possibility of Plaintiffs introducing evidence of other TRT manufacturers' misconduct, provided that the evidence can be understood without the need for extended background. CMO 59, at 6-7. The Court previously held that "*at least one* item of

[3] Excerpts of the Mitchell II Tr. are attached hereto as Ex. 1

evidence regarding another manufacturer of TRT is relevant and would not pose a substantial risk of unfair prejudice or confusion." *Id.* (emphasis added). Applying this rationale, the Court has allowed into evidence the FDA warning letter to Slate Pharmaceuticals regarding improper marketing of its TRT product (Testopel). The Court has not held that evidence of misconduct must take the form of communications from the FDA to other TRT manufacturers which AbbVie also received. AbbVie's motion should be denied to the extent that it attempts to further expand the Court's holding and limit Plaintiffs ability to offer evidence of other TRT manufacturers' misconduct which can be readily placed in context. This issue is best addressed at trial on a document by document basis.

Plaintiffs' Opposition to AbbVie's Request (d)

"Plaintiff will not introduce evidence of other AbbVie drugs, including evidence regarding AbbVie's DHT drug for hypogonadism (CMO 59, p. 6) and Depakote, including of the related Corporate Integrity Agreement ("CIA") (*id*. p. 5). If Plaintiff seeks an exception to that ruling, he must first proffer outside of the jury's presence the evidence he would introduce to demonstrate relevance including that the CIA was effective before Plaintiff's first AndroGel prescription and that AbbVie breached its CIA obligations with respect to AndroGel and obtain the Court's approval that such relevance is not outweighed by the prejudice. (*Id*. p. 6; *Nolte* Dkt. 88, 1/15/18 Minute Entry)."

Response:

Plaintiffs have agreed not to introduce evidence of other AbbVie drugs, including AbbVie's DHT drug for hypogonadism. Plaintiffs do not agree to a wholesale exclusion of evidence regarding Depakote and the Corporate Integrity Agreement (CIA) that AbbVie entered into on May 7, 2012. *See* CIA and related Press Release attached hereto as Ex. 2 & 3, respectively. As the Court previously noted, "[h]ad AbbVie entered into the corporate integrity agreement prior to the dates that plaintiffs began taking AndroGel, the agreement likely would be relevant to show that AbbVie had notice of the need to police its sales representatives and yet failed to live up to the standards to which it had agreed." CMO 59, at 6. Therefore, because Plaintiffs Harris,

Bechtholdt, and Papandrea began taking AndroGel *after* May 7, 2012, those Plaintiffs should be allowed to introduce evidence related to the CIA in accordance with the Court's reasoning in CMO 59.[4]

The CIA embodies a voluntary agreement between the Office of the Inspector General (OIG) of the United States Department of Health and Human Services (HHS) and Abbott and its successors (eventually, Abbott Laboratories and AbbVie). *See* CIA, at 1-2. Although AbbVie characterizes the CIA as "related" to Depakote, it is actually not specific to Depakote—the agreement covers all of Abbott's pharmaceutical products. *See id.* at 4. It outlines Abbott's (and by extension AbbVie's) agreement to be bound by standards relating to myriad company affairs, including the very sorts of conduct that have been at issue in bellwether trials to date: promotional activities generally; training for improper versus proper promotional activities; requirements for speaker programs; and close observation of sales representatives. These requirements go to standards by which a reasonable company and, in particular, AbbVie—the company that expressly agreed to them—could be judged. As the Court previously recognized, the CIA further provides notice to AbbVie of the need to be vigilant in ensuring that its sales force abide by certain rules, *e.g.,* promoting AndroGel only for uses for which it had been indicated, and thus shown by substantial evidence to be effective. These standards to which it promised to adhere — and evidence of AbbVie's failure to correspondingly abide by them—are directlyrelevant to Plaintiffs' negligence, misrepresentation, and punitive damage claims.

Additionally, if AbbVie seeks to introduce generalized evidence of "good company" conduct, Plaintiffs respectfully submit that such evidence "opens the door" to their prior

[4] While Plaintiff Harris first used AndroGel for a short period in 2004, his AndroGel use related to his 2012 stroke – which is the basis for his lawsuit – began in August 2012.

misconduct that resulted in the Depakote CIA. *See United States v. Bell*, 180 F. Supp. 3d 534, 538-39 (N.D. Ill. 2014) (quoting *United States v. Villegas*, 655 F.3d 662, 672 (7th Cir. 2011).

For these reasons, Plaintiffs respectfully submit that AbbVie's request for a wholesale exclusion regarding its CIA should be denied.

Plaintiffs' Opposition to AbbVie's Request (f)

"Plaintiff will not introduce any evidence relating to "men's clinics" and/or relating to allegedly inaccurate statements by doctors about TRT's benefits, unless the Plaintiff received AndroGel through a men's clinic or Plaintiff's prescriber made similar statements. (CMO 59, p. 10)."

Response:

While AbbVie's proposal may be true to the letter of the Court's ruling on this issue (*see* CMO 59, at *10), in practice and in application in future trials, AbbVie's proposed summary regarding "inaccurate statements by doctors about TRT's benefits" could lead to unintended and improper expansion of the Court's narrow ruling.

The Motion that resulted in this ruling asked the Court to exclude two specific "inaccurate statements about TRT benefits" by doctors other than the plaintiff's prescribing physician. Both statements were excluded because they could not be attributed to AbbVie's off-label marketing. Specifically, these are Trial Exhibit 31, at 17 (statement that testosterone is a "fountain of youth"), attached hereto as Ex. 4 and Trial Exhibit 1059 (statements advocating for use of TRT as an anti-aging treatment) attached hereto as Ex. 5. Defendants' Omnibus MIL, Case No. 14-cv-1748, Doc. No. 1915, at *20; CMO 59, at *10.

Plaintiffs are not asking the Court to reconsider this Order. However, there is a risk that AbbVie's proposed summary of the Court's ruling on these two statements could be misinterpreted. To avoid this risk, Plaintiffs propose the following alternative summary: "Plaintiff will not introduce any evidence relating to "men's clinics" and will not introduce the statement in

Exhibit 31 (page 17) using the phrase "fountain of youth" to describe TRT or the statements in Exhibit 1059 advocating use of TRT as an anti-aging treatment, unless the Plaintiff received AndroGel through a men's clinic or Plaintiff's prescriber made similar statements."

Plaintiffs' Opposition to AbbVie's Request (h)

"Plaintiff will not introduce evidence supporting profit disgorgement, unless and until Plaintiff first makes a proffer outside of the jury's presence that such damages are allowed under the governing state's law and obtains the Court's approval. (CMO 59, pp. 13-14)."

Response:

AbbVie's request to have a global ruling on profit disgorgement is misplaced. The issue of whether or not any individual Plaintiff has a claim for "profit disgorgement" is strictly a function of state law in each individual case. AbbVie cites to CMO No. 59, Doc. No. 1966, at *13-14, as support for its position, but the agreement reached there was specific to the *Konrad* and *Mitchell* cases, and in those cases, the plaintiffs agreed to abandon any disgorgement claims. Here, if any Wave 1 Plaintiff's home-state law permits a potential claim for profit disgorgement, AbbVie should have addressed it at summary judgment or, at a bare minimum, briefed it as an *in limine* matter in that individual case. In any event, the issue is not proper for a global disposition.

Plaintiffs' Opposition to AbbVie's Request (i)

"Neither party will introduce evidence of sales after the year of Plaintiff's injury (Konrad Dkt. 39 ruling on Hynd designations; reaffirmed in *Mitchell II* Tr., 3/12/18, pp. 804-814) or IMS/prescription data or prescription trends after the year of Plaintiff's injury. (CMO 123, p. 7)."

Response:

AbbVie incorrectly contends that Plaintiff has agreed to the stipulated language it included in Section X. i. of each of its MILs. *See, e.g.*, Abraham Doc. No. 18, at 14-15. To be clear,

Plaintiffs do agree that evidence concerning sales and IMS/prescription data should not extend beyond the year of a given plaintiff's injury.

However, the parties were unable to agree on language surrounding the admissibility of evidence concerning prescription trends. Consistent with prior trials, Plaintiffs should be permitted to present evidence of prescription trends and discussions of TRT usage that served as support for the May 2015 label change, which included a Limitation of Use regarding age-related hypogonadism and other modifications to the class TRT Indication in order to stem the tide of rampant off-label marketing and off-label TRT use. Plaintiffs' position is consistent with the Court's prior rulings on this same issue. For example, in ruling on essentially the same MIL filed by AbbVie prior to the *Konrad* and *Mitchell* trials the Court concluded, "AbbVie maintains that even if Rule 407 does not apply, evidence of label changes or other regulatory activity that post-dates plaintiffs' use of AndroGel is irrelevant to any of plaintiffs' claims. The court disagrees." *See* CMO 59, MDL Doc. No. 1966, at 3

Thus, Plaintiffs should continue to be permitted to offer evidence of prescription trends that prompted the 2015 label changes for TRT products, even if those trends cover periods of time after the injury date in a given plaintiff's case. Without this foundational evidence, the jury will have no framework for understanding the 2015 label changes. However, evidence of prescription trends after the May 2015 label change does not carry the same probative value and should be excluded. This position is also consistent with the Court's prior rulings. *See* CMO 123, Doc. No. 2672, at 7 (excluding opinions from Dr. Khera about prescription trends for TRT after the 2015 labeling changes).

Plaintiffs' Opposition to AbbVie's Request (j)

"Plaintiff will not introduce evidence or argument suggesting that Frank Sasinowski's meeting with the FDA pertained to the agency's proposal to change the TRT class label unless and

until the Plaintiff elicits evidence that gives rise to a reasonable inference that AbbVie's efforts led the FDA not to propose a label change. Plaintiff will not use characterizations like "back channel," "lobbyist," "lobbying," and similar terms, including in opening statements, unless and until first obtaining the Court's approval. (CMO 94, pp. 22-24)."

Response:

Plaintiffs oppose AbbVie's request for an *in limine* ruling limiting evidence or argument concerning the interactions between AbbVie's representative—*i.e.,* Frank Sasinowski—and FDA in relation to the TRT Class label.[5] Such a request goes well beyond the Court's prior ruling, and ignores the trial record developed thereafter that, as acknowledged in documents and AbbVie witness testimony, Mr. Sasinowski, facilitated various formal and informal interactions with the FDA on the TRT Class label.

As evidence adduced in previous trials reveals, following notice from the FDA that a "Class" label would be imposed for AndroGel (and all TRT products) limiting symptom improvement language in the label and otherwise making express limitations on the approved patient population, AbbVie engaged in a multi-pronged strategy to resist such changes. Specifically, AbbVie formed the Class label response team, led by Mr. Wojtanowski, which employed a multi-pronged defensive strategy involving formal submissions to FDA, a consumer and physician public relations campaign, and informal communications with FDA, which included the use of Mr. Sasinowski as AbbVie's agent to privately meet with FDA medical officer (Dr.

[5] Mr. Sasinowski is a lawyer with Hyman, Phelps & McNamara, P.C.

Daniel Shames), and share back informal insights.[6] The gist of AbbVie's instant request concerns those "informal" efforts.[7]

As Steven Wojtanowski[8] testified in multiple trials, Mr. Sasinowski was retained as AbbVie's representative to discuss AndroGel and the class labeling issue for claims of symptom improvement with FDA. Mitchell I Tr.[9] at 419:18-19; Konrad II Tr.[10] at 368:6-14 and 374:10-15. In that regard, Mr. Wojtanowski confirmed that Mr. Sasinowski "informal[ly]" met with FDA medical officer Dan Shames privately and on multiple occasions to discuss TRT Class labeling. Mitchell I Tr. at 419:20-420:1; Nolte Tr.[11] at 476:8-478:4; Mitchell II Tr. at 360:3-12 and 364:3-365:1; Konrad II Tr. at 369:4-14.

The Court's prior *in limine* ruling in CMO 94 excluded limited evidence relating only to one November 2005 meeting and its outcome.[12] The result of the Court's prior ruling is that Plaintiffs were not allowed to offer "questions and argument and apparent inferences" related to that one particular meeting in November 2005. Nolte Tr. at 309:25-310:8. The Court never precluded Plaintiffs from offering other broader evidence of contacts—both formal and informal—between AbbVie, or its representative Mr. Sasinowski, and FDA. Nolte Tr. at 309:25-310:1. Indeed, in *Nolte,* and in *Mitchell II* thereafter, evidence of Mr. Sasinowski's role and his

[6] *See, e.g.,* Trial Ex. 353.2 attached hereto as Ex. 6 ("Solvay Pharmaceuticals plans to provide a formal response to the draft guidance..."); Trial Ex. 352.8 attached hereto as Ex. 7 ("Develop public relations campaign to minimize negative perceptions regarding change prior to formal FDA guidance"); Trial Ex. 728 attached hereto as Ex. 8 ("D. Aberback will email Frank Sasinowski for an update on any FDA informal communications.")

[7] Notably, the term "informal" comes from AbbVie's own documents, so Plaintiffs may continue to characterize the meetings as such. *See* Trial Ex. 728 (Ex. 8) (April 10, 2005 Testosterone Class Labeling Response Team Meeting Minutes) ("D. Aberback will email Frank Sasinowski for an update on any FDA informal communications.").

[8] Mr. Wojtanowski held various high-level positions in AbbVie's and Solvay's regulatory departments.

[9] Excerpts of the Mitchell I Tr. are attached hereto as Ex. 9

[10] Excerpts of Konrad II Tr. are attached hereto as Ex. 10

[11] Excerpts of Nolte Tr. are attached hereto as Ex. 11

[12] The Court also rejected AbbVie's argument that the *Noerr-Pennington* doctrine applied to bar evidence of AbbVie's interactions with the government. CMO 94 at 22-23.

interactions with FDA—with AbbVie's knowledge and endorsement—concerning the Class labeling issue was properly adduced, notably, without objection.

As in prior trials, Plaintiff should be permitted to elicit testimony demonstrating that AbbVie retained Mr. Sasinowski as its representative to facilitate and attend various informal meetings with the FDA as part of AbbVie's Class label defense, together with the nature of those interactions/communications. *See* Ex. 728 (April 10, 2005 Testosterone Class Labeling Response Team Meeting Minutes) ("D. Aberback will email Frank Sasinowski for an update on any FDA informal communications."); *See also* Mitchell II Tr. at 363:1-364:13 (testimony from Steven Wojtanowski regarding same). The broader limitations AbbVie now seeks through its current proposal are completely unwarranted; Mr. Sasinowski's interactions with FDA on AbbVie's behalf, as its representative, are admissible in the same manner as those undertaken directly by AbbVie with FDA.

As in prior trials, Plaintiffs agree not to use words such as "back channel" or "lobbyist" when discussing Mr. Sasinowski's meetings with FDA.

CONCLUSION

Based on the foregoing, the Court should deny AbbVie's "Requests To Adopt Prior Motion *In Limine* Rulings" (b, c, d, f, h, i and j) as set forth, *supra*.

Dated: August 29, 2018

Respectfully submitted,

/s/ Christopher A. Seeger

Christopher A. Seeger
Seeger Weiss LLP
55 Challenger Rd., 6th Floor
Ridgefield Park, NJ 07660
Phone: (212) 584-0700
Fax: (212) 584-0799
Email: cseeger@seegerweiss.com

Ronald Johnson, Jr.

SCHACHTER, HENDY & JOHNSON PSC
909 Wrights Summit Parkway, Suite 210
Ft. Wright, KY 41011
Phone: (859) 578-4444
Fax: (859) 578-4440
Email: rjohnson@pschacter.com

Trent B. Miracle
SIMMONS HANLY CONROY
One Court Street
Alton, IL 62002
Phone: (618) 259-2222
Fax: (618) 259-2252
Email: tmiracle@simmonsfirm.com

Plaintiffs' Co-Lead Counsel *on behalf of*
Plaintiffs' Steering Committee

CERTIFICATE OF SERVICE

I hereby certify that on August 29, 2018, I electronically transmitted the foregoing document to the Clerk of the United States District Court using the CM/ECF system for filing and service to all parties/counsel registered to received copies in this case.

/s/ Christopher A. Seeger
Christopher A. Seeger